DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 10, 2015

Toshiba Medical Systems Corporation
% Mr. Paul Biggins
Director Regulatory Affairs/ U.S. Agent
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN, CA 92780

Re: K150427
Trade/Device Name: Vantage Titan 1.5T, MRT-1510
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH
Dated: February 18, 2015
Received: February 19, 2015

Dear Mr. Biggins:

This letter corrects our substantially equivalent letter of April 17, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150427

Device Name
Vantage Titan 1.5T, MRT-1510

Indications for Use *(Describe)*
Vantage Titan systems are indicated for use as a diagnostic imaging modality that produces cross-sectional transaxial, coronal, sagittal, and oblique images that display anatomic structures of the head or body. Additionally, this system is capable of non-contrast enhanced imaging, such as MRA.
MRI (magnetic resonance imaging) images correspond to the spatial distribution of protons (hydrogen nuclei) that exhibit nuclear magnetic resonance (NMR). The NMR properties of body tissues and fluids are:

- Proton density (PD) (also called hydrogen density)
- Spin-lattice relaxation time (T1)
- Spin-spin relaxation time (T2)
- Flow dynamics
- Chemical Shift

Contrast agent use is restricted to the approved drug indications. When interpreted by a trained physician, these images yield information that can be useful in diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. CLASSIFICATION and DEVICE NAME:

Classification Name:	**Magnetic Resonance Diagnostic Device**
Regulation Number:	**90-LNH (Per 21 CFR 892.1000)**
Trade Proprietary Name:	**Vantage Titan 1.5T**
Model Number:	**MRT-1510**

2. ESTABLISHMENT REGISTRATION: 9614698

3. Toshiba Medical Systems Corporation (TMSC)

1385 Shimoishigami
Otawara-shi, Tochigi 324-8550, Japan

4. Contact Person, U.S AGENT and ADDRESS:

U.S. Agent Name:
Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems, Inc. (TAMS)
2441 Michelle Drive
Tustin, Ca. 92780
(714) 699-7808

5. MANUFACTURING SITE:

Toshiba Medical Systems Corporation (TMSC)
1385 Shimoishigami
Otawara-shi, Tochigi 324-8550, Japan

6. DATE OF SUBMISSION:

February 18th, 2015

7. DEVICE DESCRIPTION:

The Vantage Titan (Model MRT-1510) is a 1.5 Tesla Magnetic Resonance Imaging (MRI) System. The Vantage Titan uses 1.4m short and 4.1 tons light weight magnet. It includes the Toshiba Pianissimo™ technology (scan noise reduction technology). The design of the gradient coil and the whole body coil of the Vantage Titan provides the maximum field of view of 55 x 55 x 50 cm. The Vantage Titan MRI System is comparable to the current 1.5T EXCELART Vantage Titan MRI System (K120638), cleared Jun 1, 2012 with the following modifications.

7.1 SUMMARY OF HARDWARE CHANGES

a. Main magnet has been changed from OR76 to TN150 (MRT-1510/1A) or OR200 (MRT-1510/2A).
b. System power requirements has been changed from 200V and 400V to 380/400/415/480 V.

7.2 SUMMARY OF SOFTWARE CHANGES

a. New Operating System (Windows 7)
b. WFS (Water Fat Separation) to provide water dominant images and fat dominant images.

8. SAFETY PARAMETERS

Table 1: Primary Predicate Device

Item	Vantage Titan (subject device)	Vantage Titan K120638 (Predicate Device)	Notes
Static field strength	1.5T	1.5T	Same
Operational Modes	1st Operating Mode	1st Operating Mode	Same
i. Safety parameter display	SAR dB/dt	SAR dB/dt	Same
ii. Operating mode access requirements	Allows screen access to 1st level operating mode	Allows screen access to 1st level operating mode	Same
Maximum SAR	4W/kg for whole body (1st operating mode specified in IEC 60601-2-33(2010))	4W/kg for whole body (1st operating mode specified in IEC 60601-2-33(2002))	Change*
Maximum dB/dt	1st operating mode specified in IEC 60601-2-33 (2010)	1st operating mode specified in IEC 60601-2-33 (2002)	Change*
Potential emergency condition and means provided for shutdown	Shut down by Emergency Ramp Down Unit for collision hazard for ferromagnetic objects	Shut down by Emergency Ramp Down Unit for collision hazard for ferromagnetic objects	Same

***Note:** The difference between predicate and subject device is due to the conformance of the subject device to IEC 60601-2-33 (2010)

9. IMAGING PERFORMACE PARAMETERS

No change from the previous predicate submission (K120638).

10. INTENDED USE

Vantage Titan systems are indicated for use as a diagnostic imaging modality that produces cross-sectional transaxial, coronal, sagittal, and oblique images that display anatomic structures of the head or body. Additionally, this system is capable of non-contrast enhanced imaging, such as MRA.

MRI (magnetic resonance imaging) images correspond to the spatial distribution of protons (hydrogen nuclei) that exhibit nuclear magnetic resonance (NMR). The NMR properties of body tissues and fluids are:

- Proton density (PD) (also called hydrogen density)
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- Chemical Shift

Contrast agent use is restricted to the approved drug indications. When interpreted by a trained physician, these images yield information that can be useful in diagnosis.

No changes to the previously cleared indication (K120638).

11. SUMMARY OF DESIGN CONTROL ACTIVITIES

PS Risk List for system and software are included in this submission. The test methods used are the same as those submitted in the previously cleared submissions (K120638). A declaration of conformity with design controls is included in this submission.

12. TRUTHFUL AND ACCURACY CERTIFICATION

A certification of the truthfulness and accuracy of the Vantage Titan 1.5T described in this submission is provided in this submission.

13. SUBSTANTIAL EQUIVALENCE

This device is substantially equivalent to the 1.5T EXCELART Vantage Titan MRI System (K120638), marketed by Toshiba America Medical Systems. Vantage Titan 1.5T, V3.1. MRT 1510 includes additional software features. The additional software features have the same intended use as the secondary predicate device, listed below in table one. Testing was performed using archived clinical images, simulation testing and bench (phantom) testing. This testing demonstrated that the implementation of the modifications retained the safety and effectiveness of the cleared device.

Toshiba Medical Systems Corporation believes that the Vantage Titan 1.5T (model MRT-1510) Magnetic Resonance Imaging (MRI) System is substantially equivalent to the previously cleared predicate devices referenced in this submission.

Table 2: Primary and Secondary Predicate Device

510 (k) Number	Clearance Date	Device Name	Manufacturer
K120638 Primary Predicate (System)	06/01/2012	1.5T EXCELART Vantage Titan	Toshiba America Medical Systems
K141472 Secondary Predicate (Magnet)	09/19/2014	Vantage Elan 1.5 T	Toshiba America Medical Systems
K143008 Secondary Predicate (Software Features)	RTA - 10/31/2014	Vantage Titan 3T, V2.50 Software	Toshiba America Medical Systems

Testing was done in accordance with applicable recognized consensus standards as listed below.

List of Applicable Standards

- IEC60601-1:2005
- IEC60601-1-2:2007
- IEC60601-1-8:2003,Amd.1:2006
- IEC60601-2-33:2010
- IEC60825-1: 2007
- IEC62304:2006
- IEC62366:2007
- NEMA MS-1:2008
- NEMA MS-2:2008
- NEMA MS-3:2008
- NEMA MS-4:2010
- NEMA MS-5:2010

Based upon bench testing and phantom image studies Toshiba Medical Systems Corporation believes this system has characteristics that are compatible with currently marketed devices and has proven substantively that this system performed as specified and did not raise new issues of safety and effectiveness. Furthermore, this system does not offer new intended or indicated use when compared to the predicate. Based upon this information, Toshiba believes that it has established substantial equivalence to this device and the predicate.